Supreme Court, U.S.
FILED
JAN 28 1996

No. 95-700

In the Supreme Court of the United States

OCTOBER TERM, 1995

SOFAMOR DANEK GROUP, INC., PETITIONER

v.

CLIFTON R. GAUS, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

Whether the Expert Panel on Low Back Problems is an "advisory committee" under the Federal Advisory Committee Act, 5 U.S.C. App. 3(2).

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-16a) is reported at 61 F.3d 929. The opinion of the district court (Pet. App. 17a-31a) is not reported.

JURISDICTION

The judgment of the court of appeals (Pet. App. 33a-34a) was entered on August 4, 1995. The petition for a writ of certiorari was filed on October 30, 1995. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. a. The Agency for Health Care Policy and Research (AHCPR or Agency), a component of the Public Health Service in the Department of Health and Human Services, was established by Congress in the Omnibus Budget Reconciliation Act of 1989 (OBRA 1989), Pub. L. No. 101-239, § 6103, 103 Stat. 2189, for the purpose of enhancing the quality, appropriateness, and effectiveness of health care services, and to improve access to such services. 42 U.S.C. 299b, 299b-1 (Supp. V 1993). The AHCPR carries out that mission by supporting a broad base of scientific research and by promoting improvements in clinical practice and in the organization, financing, and delivery of health care services. *Ibid.* One way in which the Agency promotes improvements in clinical practice is by supporting the development of Clinical Practice Guidelines (CPGs) through its Office of the Forum for Quality and Effectiveness in Health Care (the Forum), which was also specifically created by Congress in OBRA 1989. 42 U.S.C. 299b (Supp. V 1993). Congress directed the AHCPR to arrange, through the Forum, for the development and periodic review and updating of "clinically relevant guidelines that may be used by *physicians, educators, and health care practitioners* to assist in determining how diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically." 42 U.S.C. 299b-1(a) (Supp. V 1993) (emphasis added).

The AHCPR is required to develop an agenda of guideline topics by identifying specific diseases, disorders, and other health conditions to be given priority in the development of the guidelines. 42

U.S.C. 299b-3(a)(1) (Supp. V 1993). CPGs must be based on the best available research and professional judgment regarding the effectiveness and appropriateness of health care services and procedures. 42 U.S.C. 299b-1(b)(1) (Supp. V 1993). Congress specified alternative mechanisms by which the AHCPR may arrange for the development of CPGs: either by contracting with qualified public or nonprofit private organizations *or* by convening multi-disciplinary private-sector panels of qualified experts and health care consumers. 42 U.S.C. 299b-2(a)(1) and (2) (Supp. V 1993). In this case, the Agency utilized the latter mechanism—a private sector panel of experts and consumers. Although the AHCPR decides what the guideline topics will be, the Panels develop the CPGs, define their scope, and determine their content.[1]

b. The AHCPR solicits nominations for chairpersons and members of both expert and contractor panels through notices in the Federal Register announcing the establishment of a specific panel. C.A. App. 200. Panel members are selected primarily for their expertise and experience in the relevant academic and clinical fields. C.A. App. 158. Health care "consumers," such as patients or their family, are also represented. *Ibid.* At least two members of the panel must derive their income primarily from a source other than the performance of procedures discussed in the specific guideline being developed. 42 U.S.C. 299b-2 (Supp. V 1993). The AHCPR will not consider anyone for panel membership who has a

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[1] For example, the panel at issue in this case—the Expert Panel on Low Back Problems—limited the scope of its guideline to "acute low back problems * * * within the first three months of symptoms." See C.A. App. 302 ¶ 6.

substantial financial interest or professional affiliation that would significantly jeopardize the integrity of the guideline development process. C.A. App. 201.

c. The AHCPR has "[no] authority to review, modify, approve or disapprove the guidelines developed by [expert] panels or contractors." H.R. Rep. No. 247, 101st Cong., 1st Sess. 378 (1989). Its role is limited to funding and supporting the guideline development process, ensuring that the panels adhere to the AHCPR's evidence-based methodology, publishing and disseminating the guidelines, pilot testing the guidelines, and evaluating the extent to which the guidelines have had an effect on the clinical practice of medicine. C.A. App. 145. See 42 U.S.C. 299b-2(a), 299b-3(b)(1), 299b-3(c), 299b-3(d), 299b-3(e) (Supp. V 1993). The Agency assigns a program officer to each panel to serve as a liaison and to facilitate the panel's work. C.A. App. 181.

d. The development of CPGs by expert panels (and contractors) is conducted in accordance with a methodology established by the AHCPR. Under that methodology, all scientific evidence must be considered, the consequences of different health care options weighed, and the scientific evidence and subjective judgments supporting the chosen options explicitly described. C.A. App. 201. When scientific evidence is lacking on a particular aspect of the condition in question ("guidelines must be based on scientific evidence to the greatest extent possible," C.A. App. 145), professional judgment and group consensus are used. C.A. App. 201. All panels hold at least one open meeting, publicized in the Federal Register, to provide an opportunity for interested groups and individuals to present oral and written testimony regarding the condition under examination. *Ibid.*

A draft of a CPG is peer-reviewed by outside experts and potential users. C.A. App. 176-177. A pilot review of the guideline is also conducted in one or more clinical settings for up to three months. C.A. App. 177. Changes to the CPG based on those reviews are made at the panel's discretion. C.A. App. 176-177.

The AHCPR publishes the CPGs in four different versions: (1) the Guideline Report, a technical version containing the CPG and all supporting materials, intended for health care practitioners, researchers, educators, professional organizations, and others; (2) the Clinical Practice Guideline, containing the specific statements and recommendations for clinical treatment, intended for use by health care practitioners as a reference for clinical decision-making; (3) the Quick Reference Guide For Clinicians, an abbreviated version of the Clinical Practice Guideline intended as a day-to-day desk reference for health care practitioners; and (4) a Patient's Guide, describing the treatment options in simple terms. C.A. App. 202.

e. The AHCPR widely publicizes the release of CPGs and encourages other organizations to distribute them to their members. C.A. App. 177-178. The publication of a CPG is announced at a press conference (C.A. App. 280), and copies of the patient's brochure are sent to a variety of news media (C.A. App. 236; right column). Guideline products are available by mail through the Agency's publication clearinghouse, which has a toll-free telephone number. C.A. App. 277-278. The clearinghouse sends copies to more than 40 categories of users (C.A. App. 202), including every hospital in America and every major medical association and specialist society involved in treating the particular disease in question. C.A. App. 236

(right column). Guideline information is also available through online computer databases. C.A. App. 202. See also Pet. 20 n.18.

f. At this time, the Agency has published 15 guidelines on such topics as "Pressure Ulcers in Adults: Prediction and Prevention," "Cataract in Adults," and "Management of Cancer Pain." See Pet. 20 & n.17.

2. a. Congress enacted the Federal Advisory Committee Act (FACA) in 1972 to reduce the mushrooming cost of unnecessary blue ribbon commissions, advisory panels, and honorary boards set up by the government to advise the President and agencies. The purpose of FACA is to reduce the total number of committees, terminate those committees that have outgrown their usefulness, and increase the uniformity of procedures for those committees that are necessary. See 5 U.S.C. App. 2(b).

In addition, FACA was passed to open advisory committee processes to public scrutiny and debate. Prior to FACA, advisory committees "tend[ed] to operate in a closed environment, permitting little or no opportunity for the public to learn either about their deliberations and recommendations or about the information on which they base those recommendations." S. Rep. No. 1098, 92d Cong., 2d Sess. 6 (1972).

b. FACA defines an "advisory committee" as:

> any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof * * *, which is —
>
> (A) established by statute or reorganization plan, or

> (B) established or utilized by the President, or
>
> (C) established or utilized by one or more agencies,
>
> in the interest of obtaining advice or recommendations for the President or one or more agencies or officers of the Federal Government.

5 U.S.C. App. 3(2). Recognizing the "almost unfettered breadth" of that definition, this Court has cautioned that FACA does not cover "every formal and informal consultation between the President or an Executive agency and a group rendering advice." *Public Citizen* v. *Department of Justice*, 491 U.S. 440, 453 & n.8 (1989).

3. a. On March 18, 1991, the AHCPR announced in the Federal Register that it was establishing a panel of experts and health care consumers to develop a CPG for low back disorders and related conditions. 56 Fed. Reg. 11,452 (1991). The notice invited nominations for the panel members and chairperson. Petitioner did not respond to that notice. C.A. App. 302 ¶ 5,325.

The Expert Panel on Low Back Problems held its first meeting on November 9-10, 1991, at which time it defined the focus of the Guideline as the assessment and treatment of acute low back problems within the first three months of symptoms, and the population to be studied as working age adults from 18 to 65 years old. C.A. App. 302 ¶ 6.

A second notice appeared in the Federal Register on July 24, 1992, announcing that a public meeting of the Low Back Panel would be held on September 16, 1992, in Washington, D.C. 57 Fed. Reg. 32,991 (1992). Interested parties were invited to contribute relevant

written comments and information, and make a brief oral statement to the Panel. *Id.* at 32,992. Twenty-one speakers took advantage of that opportunity, including representatives of the American Academy of Orthopaedic Surgeons, the American Academy of Osteopathy, the American Chiropractic Association, the Association of Rehabilitation Nurses, and Liberty Mutual Insurance Company. C.A. App. 107-108. Petitioner did not send a representative and did not submit any written materials to the Panel. C.A. App. 303 ¶ 7. Petitioner also ignored a subsequent offer by the AHCPR, in correspondence with petitioner's attorneys, to inform the Panel of "any interest that [petitioner] may have in appearing before the panel as a technical expert in order to provide relevant information." C.A. App. 266-267, 303 ¶ 7. See also Pet. 4-5 & n.3.

b. Petitioner filed this action on May 24, 1994. Petitioner sought a declaration that the Expert Panel on Low Back Problems is an "advisory committee" subject to FACA and operating in violation of its requirements, and it sought an injunction prohibiting defendants from commissioning, using, or supporting the Low Back Panel, or adopting any CPG developed by the Panel. Pet. App. 18a.[2]

The district court granted the AHCPR's motion for summary judgment, holding that the Low Back Panel was not an advisory committee under FACA.

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[2] Petitioner also included a claim under the Freedom of Information Act (FOIA) for records relating to the expert panel. The AHCPR subsequently released the requested documents, except for certain records that fell within FOIA exemptions, and petitioner discontinued pursuit of the FOIA claim. Pet. App. 17a & n.1.

The court ruled that, although the Low Back Panel was established by the AHCPR, it was not established or utilized in the interest of obtaining advice or recommendations for the federal government but, rather, was established to assist health care practitioners in providing medical treatment. Pet. App. 24a-28a.

The court of appeals affirmed, emphasizing (Pet. App. 6a-7a) Congress's express statement that the purpose of the AHCPR was to establish panels to provide advice to "physicians, educators, and health care practitioners." 42 U.S.C. 299b-1(a) (Supp. V 1993). Indeed, the court described the Low Back Panel's work as "operational" because its task was to "develop[] guidelines for health care practitioners," rather than merely to "advis[e] the federal government." Pet. App. 9a. The court noted that some federal agencies were likely to use the Low Back Panel's work product in setting policy. For example, the Health Care Financing Administration (HCFA) in HHS might use the guidelines, as it would use other sources of expert information, in setting reimbursement policy under Medicare. The court concluded, however, that mere use of the Panel's work product did not mean that it was "established or utilized * * * in the interest of obtaining advice or recommendations for * * * one or more agencies or officers of the Federal Government." 5 U.S.C. App. 3(2). See Pet. App. 8a-10a. As the court of appeals explained, petitioner's contention "confuses the specific ills on which FACA is focused * * * with the use by federal entities of data specifically developed for another purpose." *Id.* at 12a.

ARGUMENT

The decision of the court of appeals is correct and does not conflict with any decision of this Court or another court of appeals.[3] Further review is not warranted.

1. Under FACA, a group constitutes an "advisory committee" if it is "established or utilized" by an agency "in the interest of obtaining advice or recommendations for * * * one or more agencies or officers of the Federal Government." 5 U.S.C. App. 3(2). See Pet. App. 6a. Thus, the core function of an advisory committee is to serve in an "advisory" role —to make recommendations or give advice regarding a specific issue to a federal agency that has opera-

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[3] Petitioner acknowledges that there is no conflict in the circuits on the question presented in this case. Pet. 9, 23. Petitioner nonetheless argues that, because in its view "[l]itigation under FACA traditionally has been undertaken in the D.C. Circuit," certiorari is warranted because "that court's decision in this case effectively may serve as the only circuit court decision on the issue." Pet. 23. In fact, numerous cases presenting issues under FACA have been litigated in other circuits. See, *e.g.*, *Idaho Dep't of Fish & Game* v. *National Marine Fisheries Serv.*, 56 F.3d 1071, 1074 n.7 (9th Cir. 1995); *Alabama-Tomigbee Rivers Coalition* v. *Department of Interior*, 26 F.3d 1103 (11th Cir. 1994); *Meyerhoff* v. *EPA*, 728 F. Supp. 613, 615 (N.D. Cal. 1990), aff'd on other grounds, 958 F.2d 1498 (9th Cir. 1992); *HLI Lordship Industries, Inc.* v. *Committee for Purchase from the Blind*, 615 F. Supp. 970, 977-979 (E.D. Va. 1985), rev'd on other grounds, 791 F.2d 1136 (4th Cir. 1986); *Dabney* v. *Regan*, 559 F. Supp. 861, 864-865 (S.D.N.Y. 1982); *Hunt* v. *NRC*, 468 F. Supp. 817, 822 (D. Okla.), aff'd on other grounds, 611 F.2d 332 (10th Cir. 1979), cert. denied, 445 U.S. 906 (1980); *Hall* v. *Siegel*, 467 F. Supp. 750, 754-755 (S.D. Ill. 1977); *Carpenter* v. *Morton*, 424 F. Supp. 603 (D. Nev. 1976).

tional responsibilities in that area. The agency may then review the advice or recommendations, modify them as it sees fit, and give them operational effect if deemed appropriate.

A CPG panel does not satisfy FACA's definition of an "advisory committee," because the panel serves an "operational," rather than an "advisory" role. See Pet. App. 9a. That is because the panel does not merely give advice concerning the content of its CPG, but instead has the operational responsibility to make all of the key decisions itself concerning the structure and content of the CPG. As Congress made clear, neither the AHCPR nor any other agency has the right or authority "to review, modify, approve, or disapprove the guidelines developed by [expert] panels or contractors." See H.R. Rep. No. 247, *supra*, at 378; see also p. 4, *supra*. Accordingly, a CPG panel cannot be said to serve in an advisory role with regard to the development of a CPG.[4] Cf. *Natural Resources Defense Council, Inc.* v. *EPA*, 806 F. Supp. 275, 278 (D.D.C. 1992) (forum of state governors providing assistance to EPA and working in an "independent, nonadvisory * * * capacity" held not to be a FACA advisory committee); *National Anti-Hunger Coalition* v. *Executive Comm'n of the President's Pri vate Sector Survey on Cost Control*, 557 F. Supp. 524, 529 (D.D.C.) (group that "do[es] not directly advise" an agency is not a FACA committee), aff'd, 711 F.2d

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[4] Because the Low Back Guideline was solely the Low Back Panel's product and not the product of a federal agency relying on Panel advice, the Guideline contains the following disclaimer: "Publication of this guideline does not necessarily represent endorsement by the U.S. Department of Health and Human Services." C.A. App. 343 (left column).

1071 (D.C. Cir. 1983). And see 41 C.F.R. 101-6.1004(g) (General Services Administration regulation) (FACA does not apply to committees that "perform primarily operational as opposed to advisory functions").

Nor does the fact that the CPG created by a panel may be consulted by federal agencies establish that the panel has given "advice or recommendations for * * * one or more agencies or officers of the Federal Government." 5 U.S.C. App. 3(2). The statute provides that CPGs are to be "clinically relevant guidelines that may be used by physicians, educators, and health care practitioners to assist in determining how diseases, disorders, and other health conditions can most effectively and appropriately be pre–vented, diagnosed, treated, and managed clini–cally." 42 U.S.C. 299b-1(a) (Supp. V 1993). Insofar as a CPG may be said to contain "advice or recommendations" at all, it thus contains advice and recommendations for "physicians, educators, and health care practitioners"—not government agencies. Federal agencies may of course take account of CPGs—and Congress no doubt intended that they do so—just as federal agencies may take account of numerous other sources of expert information in making a myriad of decisions. But the fact that a federal agency does so no more converts an expert panel into a FACA advisory commission than would the fact that the agency uses an entirely private source of information convert the producer of that source of information into a FACA advisory committee.

2. Petitioner argues that, because the Omnibus Budget Reconciliation Act requires the AHCPR to consult with HCFA in setting priorities for CPG development, see 42 U.S.C. 299b-3(a)(2)(B) (Supp. V 1993), Congress intended that the Low Back Panel

specifically (and CPG panels in general) would advise HCFA. See, *e.g.*, Pet. 10-11; see also 42 U.S.C. 1320b-12(b)(3) (Supp. V 1993). Thus, according to petitioner, the Low Back Panel was established in the interest of obtaining advice for HCFA. Petitioner's argument is mistaken.

As noted above, the statute explicitly states that the AHCPR's panels are to create guidelines that will assist "physicians, educators, and health care practitioners," 42 U.S.C. 299b-1(a) (Supp. V 1993), and it nowhere states that the panels are to advise any federal agencies. Moreover, other sources in the statute and legislative history confirm the public education function of the CPG and suggest no other. Thus, the statute requires that CPGs are to be "in formats appropriate for use by physicians, health care practitioners, providers, medical educators, and medical review organizations and in formats appropriate for use by consumers of health care." 42 U.S.C. 299b-1(b)(2) (Supp. V 1993). Notably absent from that list is any federal agency. The House Report explained that "the guidelines are intended to help physicians provide services in a more effective and appropriate manner." H.R. Rep. No. 247, *supra*, at 378. And the AHCPR itself stated that it was creating the Low Back Panel to develop "clinically relevant guidelines that may be used by physicians, educators, and health care practitioners." 56 Fed. Reg. 11,452 (1991); see Pet. App. 7a & n.23.

In any event, the fact that the AHCPR consulted with HCFA to establish its priorities for CPG development indicates that HCFA provided advice to the AHCPR—not the other way around. HCFA's advice helps the AHCPR to make the most efficient use of its limited resources by determining what are

the most significant or prominent medical conditions that physicians, educators, and health care practitioners deal with.[5] In turn, as the court of appeals explained, the production of high quality CPGs may be expected to lower Medicare costs by helping health care practitioners "treat more efficiently health conditions for which Medicare expends substantial funds." Pet. App. 9a. Thus, "in creating the [CPG] system, the Medicare program could benefit without any officer or agency of the federal government obtaining 'advice or recommendations.'" *Id.* at 10a.

3. The court of appeals' ruling is supported by this Court's decision in *Public Citizen* v. *Department of Justice*, 491 U.S. 440 (1989). In that case, the Court held that the American Bar Association's Standing Committee on Federal Judiciary was not converted into a FACA advisory committee merely because the President and the Justice Department consult the committee concerning judicial appointments. The Court explained that Congress did not intend for FACA to apply to "every formal and informal consultation between * * * an Executive agency and a group rendering advice." *Id.* at 453. The Court observed that Congress could not have meant the consequences of an overbroad reading of FACA's terms, which would

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[5] Moreover, petitioner's argument is not aided by the fact that, at several points in the manuals and guides for the development of CPGs, the AHCPR states as a general matter that the product of CPG panels may be used by "policymakers." Pet. 16-17. Those "policymakers" may refer to the Guideline, but that does not convert the Guideline into "advice or recommendations" under FACA.

> require the filing of a charter, the presence of a controlling federal official, and detailed minutes any time the President seeks the views of the [NAACP] before nominating Commissioners to the Equal Employment Opportunity Commission, or asks the leaders of an American Legion Post he is visiting for the organization's opinion on some aspect of military policy.

Ibid.

Petitioner's argument is the same one this Court rejected in *Public Citizen*. As explained above, a CPG by statute must be produced for the benefit and assistance of medical practitioners and the general public. Nonetheless, under petitioner's theory, the later use of the information in a CPG by a component of HHS converts the CPG Panel into a FACA advisory committee, retroactively subject—like the NAACP or American Legion post in the examples in *Public Citizen*—to all of FACA's requirements. As the court of appeals explained, however, *Public Citizen* "made clear that mere subsequent and optional use of the work product of a committee by a federal entity does not involve utilization under FACA." Pet. App. 6a. Since such "subsequent and optional" use is all that petitioner can allege here, petitioner's argument must fail.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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DECEMBER 1995